IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN *Ex rel.* CATHLEEN FORNEY Plaintiffs, vs. MEDTRONIC, INC., Defendant.	)	Case No. 5:15-cv-6264-EGS ORAL ARGUMENT REQUESTED

DEFENDANT MEDTRONIC, INC.'S REPLY MEMORANDUM IN FURTHER SUPPORT OF ITS MOTION TO DISMISS

INTRODUCTION

Relator's Opposition underscores the deficiencies that compel dismissal of her Complaint: her Opposition assumes or ignores the facts that she is required to plead, which are nowhere in the Complaint.[1] She assumes that practically any service provided by a medical device manufacturer to a physician who purchased a product is an impermissible kickback, yet identifies no authority that supports this novel theory. She assumes that every medical device manufacturer knows this, again without pointing to anything in her Complaint or legal authority in support. And she asserts that she does not need to plead that false claims for payment by the government actually resulted from the supposed scheme because she is entitled to assume that they must have been the inevitable result. This does not state a viable False Claims Act claim.

ARGUMENT

I. Relator Has Not Alleged What Services Were Allegedly Provided for "Free" and Therefore Has Not Plausibly Alleged that any Prohibited Remuneration Was Provided by Defendant.

Relator misstates the law when she argues that she need allege only that Medtronic provided "free services," since any service provided to the purchasers of its products violated the AKS unless one of the statute's "safe harbors" applies. (Opp. 12-13, 16-17). That is not the law. A free service can be "remuneration" under the AKS only if it provides substantial value that is independent of the purchased product. *See* Office of Inspector General, *Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731, 23735 (2003). Thus, if it provides substantial value but is not independent of the purchased product, it is not remuneration under the statute. Relator's Opposition does not offer any authority challenging this. In fact, the authority Relator cites supports Defendant. *See Ameritox, Ltd. v. Millennium Labs., Inc.*, 20 F.

[1] Relator accuses Medtronic of ignoring all but "13 of the 28 paragraphs" in her Complaint, (Opp. at 21), yet she does not cite any substantive allegations that Medtronic failed to address in its opening brief.

Supp. 3d 1348, 1351–53 (M.D. Fla. 2014) (holding that providing a free specimen cup with built-in drug-testing strips with the purchase of its laboratory services qualifies as remuneration because the preliminary test-strip results were valuable and were distinct from and independent of the laboratory testing service that was purchased). Thus, it is patently insufficient to allege that "free services" were provided without alleging (with specificity) what those services were, because not all free services potentially implicate the AKS. Furthermore, here, to the extent that Relator offers information about the services supposedly at issue, she has described conduct that is not independent of the purchased product. (*See* Medtronic's Br. at 5–8). Defendant raised this point in its original brief, and Relator has pointed to no authority whatsoever in her Opposition holding otherwise. Relator's bald assertion that these services had value is not enough. *See Cooper v. Pottstown Hosp. Co. LLC*, 651 F. App'x 114, 116 (3d Cir. 2016) ("[A]ttaching conclusory labels to ordinary, lawful acts of business does not suffice."); *Ameritox*, 20 F. Supp. 3d at 1351-53.

Relator contends that her similarly deficient assertions that Medtronic provided "free staffing" are sufficient to state a claim. (Opp. at 2, 4, 13, 14). But only two conclusory sentences in her Complaint speak to this issue—one asserts that physicians and hospitals used Medtronic's services rather than paying their own staff, (Compl. ¶ 1), and the other alleges that Medtronic "provided free staff to clinics" (Compl. ¶ 24). Such cursory allegations, which are no more than a recitation of the elements of the cause of action, do not plead facts that plausibly demonstrate an entitlement to relief or satisfy Rule 8. *See Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Critically, Relator must plead with particularity what Medtronic employees did or the supposedly free staff allegedly did, because if it did not convey substantial value or was not independent of the product, it is not remuneration under the AKS.

The one case Relator cites in support of her "free staffing" theory instead demonstrates just how deficient her Complaint is. In *United States ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp. 3d 259 (D. Mass. 2016), the court held that the relator's "free staffing" kickback theory was sufficiently well pled to survive a motion to dismiss, but the allegations in that case were far more detailed than the two conclusory sentences Relator has offered here. In *Witkin*, the relator alleged over the course of *three dozen paragraphs* details explaining how Medtronic purportedly operated diabetes clinics at its own expense, including by paying nurses to staff the clinics, and alleged that physicians often were not involved with the clinics at all, and that clinics often billed for these services. *Id.* at 269; *see also* Second Amended Complaint at ¶¶ 127-161, *United States ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp. 3d 259 (D. Mass. 2016), (No. 1:11-cv-10790-DPW). The court pointed to all of these factual allegations in allowing claims based on this theory to proceed to discovery. *Witkin*, 189 F. Supp. 3d at 269-70. Here, by contrast, Relator does not allege whether physicians participated in the supposed clinics, whether other hospital or physician staff worked in the clinics or were replaced by Medtronic employees, or what work supposedly was provided by Medtronic (or anyone else), other than generally alleging that Medtronic provided troubleshooting and technical support, which of course is not remuneration under the AKS. Relator does not even allege that Medtronic provided "free staffing" to any customers; the Complaint is silent on this. (Compl. ¶ 24). Relator was an employee in the field sales force at Medtronic. (Compl. ¶ 4). These glaring gaps in her pleadings all relate to facts that she should be more than able to plead if she could do so.

II. Relator Does Not Allege a Knowing and Willful Violation of the AKS.

The novelty, and the vagueness, of Relator's theory as to what kind of independent service might at issue here leaves the Court with no basis to conclude that Medtronic knew the services it allegedly provided were illegal, and that Medtronic nevertheless acted with the intent

"to do something the law forbids." *United States v. Goldman*, 607 F. App'x 171, 174 (3d Cir. 2015). This is the *mens rea* requirement of the AKS, and a *prima facie* AKS violation cannot be pleaded without it. *Id.*

None of the intent arguments in the Opposition is persuasive. Relator highlights a single quotation from the AdvaMed Code, (Opp. at 15), but once again ignores that the Code also plainly states that the "safe and effective use of sophisticated electronic, *in vitro*, diagnostic, surgical or other Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education, training, service and technical support." AdvaMed Code at 2.[2] The AdvaMed Code provides no support for Relator's theory here.

Relator also argues that Medtronic's top executives were aware that using Google Calendar and other software to track surgeries violated HIPAA, which she alleges seemingly to demonstrate knowing kickbacks as opposed to a standalone HIPAA violation. (Opp. 30-31). But this argument rests on the assumption that the only reason to track surgeries would be to provide impermissible kickbacks—an allegation that Relator does not make in the Complaint and appears to contradict elsewhere in her Opposition. (Opp. at 5) (suggesting that assistance with device implantation is permissible).

Furthermore, all Relator actually has alleged is that Medtronic's 10-K for 2013 discussed the possibility of enterprise-wide HIPAA risk when it said: "We are committed to maintaining the security and privacy of patients' health information and believe that we meet the expectations of the HIPAA rules. Some modifications to our systems and policies may be necessary, but the framework is already in place." (Compl. ¶ 27). Relator is entitled to only the *reasonable* inferences from the facts she alleges, *see Iqbal*, 556 U.S. at 678, and this statement does not, on its face, support the inference that Medtronic knew that it was violating HIPAA in the course of a

[2] https://www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf

kickback scheme. In fact, it says Medtronic believed it was *not* violating HIPAA. Indeed, the statement is not even a "fact" that applies to the alleged scheme; it has nothing to do with the procedures supposedly at issue in this lawsuit.

Relator also cites two OIG guidance documents warning that free, significantly discounted, or "below fair market value" services may violate the AKS, but this guidance simply states the general legal rule—which Medtronic is not disputing. (Opp. at 15). Both documents assume that the services are independent of the products sold because the issue is whether a discount on what is normally charged for the service at issue was offered in order to induce a purchase of something else. They are thus entirely consistent with OIG's later guidance clarifying that services provided by manufacturers are remuneration only if they have substantial value independent of the products purchased. 68 Fed. Reg. 23731, 23735 (2003). When assessing whether a free service is remuneration under the AKS, the question OIG asks is the exact question Relator does not answer in her Opposition or her Complaint: Do the services have a substantial value that is independent of the product purchased?

Last and least, Relator seeks an adverse inference drawn from Medtronic's "failure" to seek an OIG advisory opinion. But what she is asking for is precluded by law. The statute empowering such advisory opinions provides that "[a] party's failure to seek . . . an advisory opinion may not be used as evidence to prove that the party intended to violate federal health care statutes." *Zimmer, Inc. v. Nu Tech Med., Inc.*, 54 F. Supp. 2d 850, 855 (N.D. Ind. 1999); 42 U.S.C. § 1320a-7d(b)(4)(B).

III. Relator Does Not Allege any False Claims Act Violation with Sufficient Specificity.

Relator's legal position as to the pleading standard is this: simply saying that false claims were submitted is sufficient to state a cause of action under the False Claims Act with the

particularity required by Rule 9(b). (Opp. at 28 (citing *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 158 (3d Cir. 2014)). In her view, so long as her hypothesized scheme could conceivably result in the submission of false claims, she is entitled as a matter of law to assume that false claims were submitted. (Opp. at 26).

Relator stretches *Foglia* too far. In *Foglia*, the Third Circuit held that to survive dismissal, a complaint must contain "reliable indicia that lead to a strong inference that [false] claims were actually submitted." 754 F.3d at 156. The court found that there was a sufficiently strong inference in that case because the alleged scheme itself was a scheme to submit falsely inflated bills to Medicare for vials of medication that had not been used. *Id.* at 158. In contrast, Relator alleges here only that free services were provided; she offers no specific allegations about any claims, and she completely fails to connect the supposed kickbacks to resulting false claims, which, if they existed, were merely incidental, not the raison d'être of the alleged fraud as in *Foglia*. *See also Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 32 (1st Cir. 2016) (upholding the dismissal of a complaint because its "factual and statistical evidences struggles to connect [its] allegations with the submission of any false claims to the government."). The Third Circuit noted that *Foglia*, with its explicit false-billing scheme, was a "close case" under Rule 9(b). Here, where there is no false-billing or false claims-submission scheme, Relator is required to—but did not—plead factual and statistical evidence connecting her allegations to the submission of false claims. Relator did not even allege attempts to provide any of the "reliable indicia" found to be barely sufficient in *Foglia*.

The Supreme Court's recent decision in *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), emphasized that because "the False Claims Act is not an all-purpose antifraud statute," the most important factor in determining liability is the nature and

content of the claim. *Id.* at 2003.[3] Consistent with this understanding of the statute, courts have held that to satisfy Rule 9(b), a relator must, at a minimum, allege "factual or statistical evidence to strengthen the inference of [false claims] beyond possibility." *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 10 (1st Cir. 2016) (emphasis added).[4] The Third Circuit in effect followed this approach in *Foglia* when it held that the details of the particularly alleged scheme in that case made it more likely than not—i.e., probable—that false claims were submitted. Here, however, Relator provides no allegations supporting a conclusion that false claims were submitted at all, let alone as a result of any AKS violation. Relator's conclusory approach to pleading false claims does not suffice.

CONCLUSION

Relator's allegations do not rise above supposition. Relator has no idea what services may have crossed the line and what services didn't, and as to what procedures, or if she knows she doesn't say. The Complaint should be dismissed in its entirety, with prejudice.

[3] Indeed, under the rubric the Supreme Court adopted in *Escobar*, the first step to determining whether the FCA has been violated is to analyze the content of the claim(s) that were submitted to determine in what way they may be materially false. *See id.* at 2003-04.

[4] To the extent there is anything to the contrary in *United States ex rel. Underwood v. Genentech*, 720 F. Supp. 2d 671 (E.D. Pa. 2010), which was decided before *Foglia* and *Escobar*, it is no longer good law.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The foregoing document was filed electronically on May 30, 2017 and is available for viewing and downloading via the Eastern District of Pennsylvania's Electronic Case Filing (ECF) system. The foregoing document will be sent electronically via the ECF system to the registered participants as identified on the Notice of Electronic Filing, including the Plaintiff States per the Court's order of December 23, 2016 (Dkt. No. 14). I certify that on May 30, 2017, in addition to the Notice of Electronic Case Filing automatically generated by the ECF system, I caused the foregoing document to be served via email upon the following:

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